EXHIBIT A

U.S. Food & Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Lifeway Foods, Inc. 2/18/11

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Chicago District
550 West Jackson Blvd., 15th Floor
Chicago, Illinois 60661
Telephone: 312-353-5863

February 18, 2011

WARNING LETTER

CHI-05-11

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Julie Smolyansky, President and CEO
Lifeway Foods, Inc.
6431 Wast Oakton Street
Morton Grove, IL 60053

Dear Ms. Smolyansky:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address http://lifeway.net[1] and labels for some of your products and has determined that the products, “Lifeway Kefir,” “Lifeway ProBoost™,” **“**BioKefir Blackberry”and “ProBugs Goo-Berry Pie” are promoted for conditions that cause the product to be drugs under Section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that these products are drugs because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease. The marketing of this product with these claims violates the Act.

Examples of some of the claims for **“Lifeway Kefir”** products observed on your web site include:

In the table with the heading, “How Lifeway Kefir Helps You”:

For “Celiac Disease”:

- “[M]ay help alleviate the severity of celiac disease…due to the anti-inflammatory properties of its 112 live and active Probiotic cultures.”

For “Crohn’s and Colitis”:

- “Reduces the severity of symptoms, lessening abdominal pain, diarrhea and nausea.”

For "Immune Deficiency":

- "Probiotics stimulate the production of immune cells, suppress inflammatory response and help to control intestina inflammatory diseases."

For "Infantile Colic":

- "[G]iving probiotics to breastfed, colicky infants overwhelmingly improves symptoms within one week of treatment."

For "Seasonal Allergies":

- "[A]lleviate seasonal allergic rhinitis..."

For "Yeast Infections":

- "[R]educe both the number and severity of yeast infections."

For your **"Lifeway ProBoost"** product, you make the following claim on your website:

- "[H]elpful at alleviating...symptoms of irritable bowel syndrome. It can even have a positive effect...fighting cancer."

We also obtained labels for your **"**BioKefir Blackberry" and "Pro Bugs Goo-Berry Pie" products and they contain the following claims:

BioKefir Blackberry:

- "The antioxidant blend also contains resveratrol that is believed to help ward of carcinogens..."

ProBugs Goo-Berry Pie:

- "[F]ocusing on getting rid of all the bad bacteria."

Your products as noted above are not generally recognized as safe and effective for the above referenced uses and therefore, the products are "new drugs" under Section 201(p) of the Act [21 U.S.C. § 321(p)]. Under Section 301(d) and 505(a) of the Act [21 U.S.C. §§ 331(d) and 355(a)], a new drug may not be introduced or delivered for introduction into interstate commerce unless an FDA-approved application is in effect for it. The introduction into interstate commerce of unapproved new drugs without approved applications violates these provisions of the Act.

Furthermore, because your products are offered for conditions that are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners, adequate directions cannot be written so that a layman can use the products safely for their intended uses. Thus, the labeling fails to bear adequate directions for its intended uses, causing the products to be misbranded under Section 502(f)(1) of the Act, [21 U.S.C. § 352(f)(1)]. The introduction of a misbranded drug into interstate commerce is a violation of § 301(a) of the Act, [21 U.S.C. § 331(a)].

The above violations are not meant to be an all-inclusive list of deficiencies in your products and their labeling. While reviewing your website, we noticed that you were promoting other products for disease treatment and/or prevention. The unlawful disease treatment and prevention claims on your website were too numerous to list in this letter. It is your responsibility to ensure that products marketed by your firm comply with the Act and its implementing regulations. We advise you to review your website, product labels, and other labeling and promotional materials for you products to ensure that the claims you make for your products do not cause them to violate the Act.

You should take prompt action to correct the violations described above and prevent their future recurrence. Failure to d so may result in enforcement action without further notice. The Act authorizes the seizure of illegal products and injunctions against manufacturers and distributors of those products [21 U.S.C. §§ 332 and 334].

Please notify this office, in writing, within fifteen (15) working days of the receipt of this letter, as to the specific steps you have taken to correct the violations noted above and to assure that similar violations do not occur. Include any documentation necessary to show that correction has been achieved. If corrective actions cannot be completed within fifteen working days, state the reason for the delay and the time within which the corrections will be completed.

Please send your reply to the Food and Drug Administration, Attention: Rosemary Sexton, Compliance Officer, at the address above. If you have any questions regarding any issues in this letter, please contact Ms. Sexton at 312-596-4225 or rosemary.sexton@fda.hhs.gov.

Sincerely,
/S/
Scott J. MacIntire
District Director